## 510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

K082119


**Submitter's Name:** Toshiba America Medical Systems, Inc.
**Address:** PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
**Contact:** Paul Biggins, Director Regulatory Affairs
**Telephone No.:** (714) 730-5000


**Device Proprietary Name:** SSA-790A, Aplio XG Version 3.0
**Common Name:** Diagnostic Ultrasound System

AUG 12 2008

**Classification:**

**Regulatory Class:** II
**Review Category:** Tier II

- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Fed. Reg. No.: 892.1570]

**Identification of Predicate Devices:**
Toshiba America Medical Systems believes that this device is substantially equivalent to:

1. Toshiba SSA-790A, Aplio XG Version 2.2 Diagnostic Ultrasound; 510(k) K081065
2. Hitachi Medical Systems America Inc. HI VISION 900 Diagnostic Ultrasound Scanner 510(k) K063518

**Device Description:**
The Aplio XG Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

**Intended Use:**
The Aplio XG is intended to be used for the following types of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

**Safety Considerations:**
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 - 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082119
Trade/Device Name: Aplio XG v3.0 SSA-790A
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 26, 2008
Received: July 28, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 12, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio XG v3.0 SSA-790A, as described in your premarket notification:

Transducer Model Number

| | |
|---|---|
| PVT-375BT | PET-510MB |
| PVT-661VT | PST-25BT |
| PLT-1202S | PLT-604AT |
| PC-20M | PLT-704AT |

PLT-805AT
PLT-1204AT
PLT-1204AX
PVT-382BT
PVT-674BT
PVT-575MV
PVT-770RT
PST-30BT
PST-50AT
PST-65AT
PLT-704SBT
PLT-1204MV
PVT-382MV
PVT-681MV
PET-511BTM
PC-50M
PLT-705BTF
PLT-705BTH
PLT-1204BT
PLT-1204BX
PVT-745BTV

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

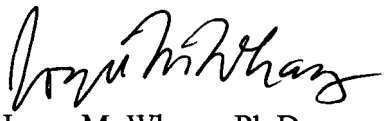
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to

proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVT-575MV
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

**Previous 510(k) for this device K081065**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)
**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVT-770RT
510(k) Number(s)

| | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | P | P | P | P | P | P | | P | | | | P |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

**(Division Sign-Off)**
**Division of Reproductive, Abdominal and Radiological Devices**
**510(k) Number** K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PST-30BT

510(k) Number(s)

| | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | P | P | P | P | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | P | P | P | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Cardiac | P | P | P | P | P | P | P | P | P | P | | P |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K08099

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PST-50AT

510(k) Number(s)

| | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | | | P | P | P | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | | | P | P | P | | | P |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | P | P | P | P | | | P | P | P | | | P |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;

**Previous 510(k) for this device K0810650**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications For Use Form

System Transducer X

Model PST-65AT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | | | P | P | P | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | | | P | P | P | | | P |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | P | P | P | P | | | P | P | P | | | P |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082119

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PLT-704SBT

510(k) Number(s)

| | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082119

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications For Use Form

System ~~Transducer~~ X

Model PLT-1204MV

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PVT-382MV

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | | P | | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

**Previous 510(k) for this device K0810650**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ____ Transducer X
Model PVT-681MV
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | P | P | P | P | P | P | | P | | | | P |
| Transvaginal | P | P | P | P | P | P | | P | | | | P |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PET-511BTM
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | P | P | P | P | | | P | P | P | | | P |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer: X

Model PC-50M

510(k) Number(s) _____

| | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | P | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | P | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | P | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: _____

**Previous 510(k) for this device k081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-705BTF
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | N | N | N | N | N | N | | N | | | | N |
| Intraoperative (Specify) | N | N | N | N | N | N | | N | | | | N |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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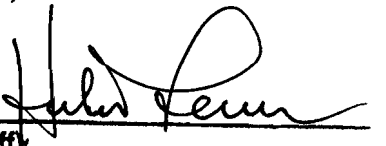
Prescription Use (Per 21 CFR 801.109) 
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-705BTH
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | N | N | N | N | N | N | | N | | | | N |
| Intraoperative (Specify) | N | N | N | N | N | N | | N | | | | N |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System: Transducer: X

Model: PLT-1204BT

510(k) Number(s):

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | N | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | N | N | N | N | N | N | N | N | | | | N |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | N | N | N | N | N | N | N | N | | | | N |
| Musculo-skeletal Conventional | N | N | N | N | N | N | N | N | | | | N |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082119

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications For Use Form

System _X_ Transducer___
Model Aplio XG v3.0 SSA-790A
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | P | | | P |
| Intraoperative (Specify) | P | P | P | P | P | | | P | | | | P |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | P | P | P | | | P |
| Small Organ (Specify)* | P | P | P | P | P | N | N | P | | | | P |
| Neonatal Cephalic | P | P | P | P | P | P | | P | P | | | P |
| Adult Cephalic | P | P | P | P | P | P | | P | P | | | P |
| Cardiac | P | P | P | P | P | P | P | P | P | P | | P |
| Transesophageal | P | P | P | P | | | P | P | P | | | P |
| Transrectal | P | P | P | P | P | P | | P | | | | P |
| Transvaginal | P | P | P | P | P | P | | P | | | | P |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | N | N | P | P | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | N | N | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | N | N | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

All indications were previously reported via k081065

* : For example: thyroid, parathyroid, breast, scrotum and penis

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Prescription Use (Per 21 CFR 801.109)11

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVT-375BT
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | | P | | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PVT-661VT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | P | P | P | P | P | P | | P | | | | P |
| Transvaginal | P | P | P | P | P | P | | P | | | | P |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For 510(k) Form

System ___ Transducer X
Model PLT-1202S
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | P | P | P | P | P | | | P | | | | P |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications for Use Form

System ___, Transducer X

Model PC-20M

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | P | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | P | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | P | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: ___

**Previous 510(k) for this device K081065**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications for Use Form

System ___ Transducer X
Model PET-510MB
510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | P | P | P | P | | | P | P | P | | | P |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;

Previous 510(k) for this device K081065

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications for Use Form

System ___ Transducer X

Model PST-25BT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | P | P | P | P | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | P | P | P | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Cardiac | P | P | P | P | P | P | P | P | P | P | | P |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device K081065

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model PLT-604AT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications Use Form

System ___ Transducer X

Model PLT-704AT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

# Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X

Model: PLT-805AT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications for Use Form

System — Transducer X

Model PLT-1204AT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications For Use Form

System: Transducer: X

Model: PLT-1204AX

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow * | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

## Diagnostic Ultrasound Indications for Use Form

System ___ Transducer X

Model PVT-382BT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | | P | | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications for Use Form

System Transducer 2

Model PVT-674BT

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | | | | P |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previous 510(k) for this device K081065

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications for Use Form

System Transducer X

Model PLT-1204BX

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | N | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | N | N | N | N | N | N | N | N | | | | N |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | N | N | N | N | N | N | N | N | | | | N |
| Musculo-skeletal Conventional | N | N | N | N | N | N | N | N | | | | N |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119

Diagnostic Ultrasound Indications for Use Form

System [illegible] Transducer [illegible]

Model PVT-745BTV

510(k) Number(s)

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | THI | M | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | N | N | N | N | N | N | | N | | | | N |
| Intraoperative (Specify) | N | N | N | N | N | N | | N | | | | N |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082119